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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Charles L. Magness and Shawn P. Iadonato
Application No.	: 09/707,576
Filed	: November 6, 2000
For	: SYSTEM AND METHOD FOR SELECTIVELY CLASSIFYING A POPULATION
Examiner	: Anna Skibinsky, Ph.D.
Art Unit	: 1631
Docket No.	: 55382-3
Date	: March 17, 2008

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PRE-APPEAL BRIEF REQUEST FOR REVIEW: ARGUMENTS

Commissioner for Patents:

In response to the Advisory Action dated December 20, 2007, Applicants herewith submit arguments in support of the accompanying Request for a Pre-Appeal Conference.

REMARKS

The Advisory Action dated December 20, 2007 maintained the grounds of rejection of the Office Action dated November 16, 2007, and declined to enter the proposed Amendments set forth in the Response to the same Office Action on November 16, 2007. Applicants submit this request for review of the rejection, and for entry of the Amendments filed on November 16, 2007 on the grounds that the Amendments responded directly to the Examiner's remaining rejections and were clearly intended to cancel most of the claims and place the few remaining claims in condition for allowance.

1. Claims 1-19, 47, 49, 50, and 51, stand rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter.

2. Claims 1-10, 14-26, 28, 31-44, and 46-55, stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

3. For reasons stated below, Applicants believe the above claim rejections have been overcome and should be withdrawn. Alternatively, Applicants submit that the Amendments filed November 16, 2007, should be entered, which further describe the claimed subject matter. In either event, Applicants submit that the present pending claims comply with the patentability requirements.

Arguments

1. With regard to the claim rejections under 35 U.S.C. § 101, Applicants respectfully submit that in the Office Action dated June 16, 2006, the Examiner suggested that this rejection could be overcome by, "includ[ing] a step of displaying the data for a user. Hence, the data would become concrete, tangible, and useful." *See* page 5, Office Action dated June 16, 2006.

Despite Applicants' amendment to the claims reciting a step of displaying the data for a user in the Response to the June 16, 2006 Office Action, this rejection has been maintained. *See* pages 3 and 16, Response dated December 18, 2006. Thus, Applicants respectfully submit that this rejection should be withdrawn.

2. With regard to the claim rejections under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, Applicants respectfully submit that the Examiner has

failed to consider the originally filed application as well as the Affidavits previously filed. Applicants submit that no undue experimentation is required to practice the presently pending claims. Applicants note that remarks and Affidavits in support of the claims have been filed previously by Drs. Lesser and Myers. *See* pages 17-26, and corresponding Affidavits of Response filed December 18, 2006. An Affidavit was also filed previously by Dr. Iadonato in a Supplemental Response dated February 22, 2007.

Applicants submit that each point of the Examiner's prior rejections has been addressed in previous Responses. Applicants reiterate that the present claims relate to a computer-implemented method for identification of a drug target associated with a selected biological condition, comprising: using a computer to analyze stored data related to medical histories of a population; using a computer to analyze stored data related to medical test results for the population; and based on computer analysis of the data related to the medical histories and the data related to the medical test results, classifying the population into at least two phenotypic sub-populations defined as at risk and affected (ARA), whose members have ever been affected by the selected biological condition, and at risk and unaffected (ARU), whose members ought to be affected by the selected biological condition at the present time based on a risk analysis, but are unaffected by the selected biological condition at the present time; performing a computer analysis of genetic data from the ARA sub-population and the ARU sub-population to identify genetic variations therebetween; displaying the data for a user; and using data related to the identified genetic variations between the ARA sub-population and the ARU sub-population to identify the drug target associated with the selected biological condition.

Applicants submit that an element of the present invention is that prior knowledge of the genetic basis of a disease is not required for identification of a drug target. As set forth at line 22, page 10 – line 25, page 11, of the originally filed application, population members may be classified according to phenotype, and further characterized by genotype. In standard techniques, the disease itself is studied by analyzing the defective genes and proteins of people afflicted with the disease or condition. In the present disclosure, drug targets are identified through the use of ARU – at risk, unaffected – populations to discover the phenotype of people who are naturally resistant

to the disease or condition. The differences that are found in the unaffected population become the basis of the treatment for that disease.

Applicants submit that Figures 3-5 of the originally filed application provide the basis for defining the epidemiological ARA and ARU populations, as well as testing the sub-populations. In this way, a candidate drug target (whether a small molecule, polynucleotide, polypeptide, antibody, or other biological or chemical target) is determined based on the identification of the genetic differences in the phenotypic defined populations and/or sub-populations. In most cases, the target is easily discernible, for example, the case where a genetic difference causes one at-risk group of individuals to be unaffected but another at-risk group of individuals is affected. For such a case, the person of skill in the art need only to identify the biological manifestation of the genetic difference, whether it is an increase, a decrease, or a change in the protein encoded by or regulated by the identified mutations. Without regard to the outcome of this last step, as soon as the target has been identified by the presence of mutations that associate with the ARU versus the ARA group, then the presently pending claims have been achieved. *See for example,* line 21, page 17 –line 13, page 21, and line 18, page 25 – line 8, page 30, of the originally filed application.

Applicants further maintain that the Examiner has not afforded the expert affidavits "meaningful consideration," as required under *In re Sullivan*, 498 F.3d 1345, 1356 (Fed. Cir. 2007). In *Sullivan*, the court stated that the declarations supported the applicants' arguments and had the Board considered or reviewed the submitted declarations in any meaningful way, it might have come to a different conclusion than it otherwise had. *Id.* Thus, when a patent applicant puts forth rebuttable evidence, the Board must consider that evidence.

Applicants respectfully submit that the Affidavits verify that use of the presently pending claims does result in identification of candidate drug targets, as exemplified by the identification of drug targets related to Hepatitis C. In fact, candidate drug targets identified by the presently pending claims has resulted in an anti-viral therapy for Hepatitis C, which has already moved to the state of clinical trials. Thus, the evidence presented in the Affidavits confirms that the presently pending claims are fully enabled by the instant application.

3. Finally, Applicants respectfully note that they attempted to cancel claims 1-19, 47, 49, 50, and 51 in the Response filed November 16, 2007. However, since the Examiner refused to enter the Amendments, the claims remain pending. Applicants again request cancellation of claims 1-19, 47, 49, 50, and 51, solely to expedite prosecution of the remaining claims and without prejudice to filing future continuing applications on the canceled subject matter. Canceling claims 1-19, 47, 49, 50, and 51 will render moot the rejection under 35 U.S.C. § 101.

Applicants respectfully submit that the claim amendments were improperly refused entry, as a new search would not be necessary if the Amendments filed on November 16, 2007, were entered. Applicants submit that the Amendments focused the claims on one specific category ("disease") out of a defined group ("biological condition"), as set forth in the application, for example, at page 8 of the originally filed specification. Applicants further note that—even prior to the Amendments of November 16, 2007—claim 20 included the step of "defining disease characteristics," including medical tests, and risk characteristics. Likewise, dependent claim 23 recited specific "disease characteristics." *See* Response, pages 3-4.

Thus, Applicants respectfully request that the Amendments set forth in the November 16, 2007, Response to the Office Action should properly be entered as the amended subject matter would not require a new search, and would not burden the Office.

Accordingly, Applicants respectfully request a Notice of Allowance or a Pre-Appeal Conference.

Respectfully submitted,
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